



PTO/SB/08b(08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/596,479
Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	10935-35

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	RUNKELSTEIN, J. D., "The metabolism of homocysteine: pathways and regulation", Eur J Pediatr, 1998, pp. S40-S44, Vol. 157, No. 2.	
	2.	CHAO, Chia-Lun, et al., "The graded effect of hyperhomocysteinemia on the severity and extent of coronary atherosclerosis", Atherosclerosis, 1999, pp. 379-386, Vol. 147.	
	3.	SPENCE, J. David, et al., "Plasma homocysteine concentration, but not MTHFR genotype, is associated with variation in carotid plaque area", Stroke, 1999, pp. 969-973, Vol. 30.	
	4.	VASAN, Ramachandran S., et al., "Plasma homocysteine and risk for congestive heart failure in adults without prior myocardial infarction", JAMA, 2003, pp. 1251-1257, Vol. 289, No. 10.	
	5.	UBBINK, Johan B., et al., "Vitamin requirements for the treatment of hyperhomocysteinemia in humans" Human and Clinical Nutrition, 1994, pp. 1927-1933, Vol. 124.	
	6.	HACKAM, Daniel G., et al., "What level of plasma homocysteine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocysteine levels above and below 14 µmol/L", American Journal of Hypertension, 2000, pp. 105-110, Vol. 13, No. 1.	
	7.	ANWAR, Wafaa, et al., "Hyperhomocysteinemia is related to reduced glomerular filtration and folate, but not to methyltetrahydrofolate-reductase and methionine synthase polymorphisms, in supplemented end-stage renal disease patients undergoing hemodialysis", Clin Chem Lab Med, 2001, pp. 747-752, Vol. 39, No. 8.	
	8.	ARNADOTTIR, M., et al., "The effect of reduced glomerular filtration rate on plasma total homocysteine concentration", Scand J Clin Lab Invest, 1998, pp. 41-46, Vol. 56.	
	9.	HOUSE, Andrew, et al., "Effect of multivitamins on plasma homocysteine levels in patients on haemodialysis", ASAIO Journal, 1999, pp. 94-97, Vol. 45.	
	10.	SPENCE, J. David, et al., "Effect of usual doses of folate supplementation on elevated plasma homocysteine in hemodialysis patients: no difference between 1 and 5 mg daily", Am J Nephrol, 1999, pp. 405-410, Vol. 19.	
	11.	ELIAN, Kelly M., et al., "Hydroxocobalamin reduces hyperhomocysteinemia in end-stage renal disease", Metabolism, 2002, pp. 881-886, Vol. 51, No. 7.	
	12.	BOSTOM, Andrew G., et al., "Short term betaine therapy fails to lower elevated fasting total plasma homocysteine concentrations in hemodialysis patients maintained on chronic folic acid supplementation", Atherosclerosis, 1995, pp. 129-132, Vol. 113.	
	13.	HOUSE, Andrew, et al., "Randomized trial of high-flux vs low-flux haemodialysis: effects on homocysteine and lipids", Nephrology Dialysis Transplantation, 2000, pp. 1029-1034, Vol. 15.	
	14.	VRIESE, An S., et al., "Effect of dialyzer membrane pore size on plasma homocysteine levels in haemodialysis patients", Nephrology Dialysis Transplantation, 2003, pp. 2596-2600, Vol. 18.	

copies not provided

Examiner Signature	/Timothy Thomas/	Date Considered	5/5/2008
--------------------	------------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08b(08-03)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	10/596,479
Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	10935-35

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	15.	FRIENDMAN, Alton N., et al., "The effect of N-acetylcysteine on plasma total homocysteine levels in hemodialysis: a randomized, controlled study", American Journal of Kidney Diseases, 2003, pp. 442-446, Vol. 41, No. 2.	
	16.	VENTURA, Paolo, et al., "Urinary and plasma homocysteine and cysteine levels during prolonged oral N-acetylcysteine therapy", Pharmacology, 2003, pp. 105-114, Vol. 68.	
	17.	LAUTERBURG, Bernhard, et al., "Depletion of total cysteine, glutathione, and homocysteine in plasma by ifosfamide/mesna therapy", Cancer Chemother Pharmacol, 1994, pp. 132-138, Vol. 35.	
	18.	PENDYALA, Lakshmi, et al., "Intravenous ifosfamide/mesna is associated with depletion of plasma thiols without depletion of leukocyte glutathione", Roswell Park Cancer Institute, 2000, pp. 1314-1321, Vol. 8.	
	19.	PENDYALA, Lakshmi, et al., "Modulation of plasma thiols and mixed disulfides by BNP7787 in patients receiving paclitaxel/cisplatin therapy", Cancer Chemother Pharmacol, 2003, pp. 376-384, Vol. 51.	
	20.	JACOBSEN, Donald W., et al., "Rapid HPLC determination of total homocysteine and other thiols in serum and plasma: sex differences and correlation with cobalamin and folate concentrations in healthy subjects", Clin. Chem., 1994, pp. 873-881, Vol. 40, No. 8.	
	21.	BOSTOM, Andrew G., et al., "Hyperhomocysteinemia and traditional cardiovascular disease risk factors in end-stage renal disease patients on dialysis: a case-control study", Atherosclerosis, 1995, pp. 93-103, Vol. 114.	
	22.	BOSTOM, Andrew G., "Homocysteine: 'expensive creatine' or important, modifiable risk factor for arteriosclerotic outcomes in renal transplant recipients?", J Am Soc of Nephrol, 2000, pp. 149-151, Vol. 11.	
	23.	DUCLOUX, Didier, et al., "Hyperhomocysteinemia in hemodialysis patients: folic acid combination with vitamin B6 and B12", Nephrol Dial Transplant, 2002, pp. 865-870, Vol. 17.	
	24.	SIGIT, Joseph I., et al., "Total plasma homocysteine and related amino acids in end-stage renal disease (ESRD) patients measured by gas chromatography-mass spectrometry - comparison with the Abbott IMx homocysteine assay and the HPLC method", Clin Chem Lab Med, 2001, pp. 681-690, Vol. 39, No. 6.	
	25.	SORIA, C., et al., "Concentrations of total homocysteine in plasma in chronic renal failure", Clinical Chemistry, 1990, pp. 2137-2138, Vol. 36, No. 12.	
	26.	SQUID, Abdul-Kader, et al., "Blood thiols following amifostine and mesna infusions, a pharmacologic oncology group study", The American Society for Pharmacology and Experimental Therapeutics, 2001, pp. 1460-1466, Vol. 29.	
	27.	YAMAMOTO, Nobuko, et al., "Effect of cysteine on expression of cystathionine β -synthase in the rat liver", J. Nutr. Sci. Vitaminol., 1995, pp. 197-205, Vol. 41.	
	28.	GOREN, Marshal P., et al., "Reduction of dimesna to mesna by the isolated perfused rat liver", Cancer Research, 1968, pp. 4358-4362, Vol. 58.	

copies not provided

Examiner Signature	Timothy Thomas	Date Considered	5/5/2008
--------------------	----------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
 Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.95. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Application Number	10/596,479
Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	10935-35

[illegible]

Examiner Signature	/Timothy Thomas/	Date Considered	5/5/2008
-----------------------	------------------	--------------------	----------

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. Do NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.